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| APPLICATION NO                                      | ). F | FILING DATE     | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |  |
|---|------|-----------------|------------------------|-------------------------|------------------|--|
| 10/617,708 07/14/2003                               |      | Frank Beerwerth | 056427-5004-01         | 4185                    |                  |  |
| 9629  | 7590 | 08/25/2004      |                        | EXAMINER                |                  |  |
|   |      | & BOCKIUS LLP   | VERBITSKY, GAIL KAPLAN |                         |                  |  |
| 1111 PENNSYLVANIA AVENUE NW<br>WASHINGTON, DC 20004 |      |                 |                        | ART UNIT                | PAPER NUMBER     |  |
|   |      |                 |                        | 2859                    |                  |  |
|   |      |                 |                        | DATE MAILED: 08/25/2004 |                  |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

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|  | Application No.   | Applicant(s)                |  |  |  |  |  |
|--|---|-----------------------------|--|--|--|--|--|
| Office Astice Comments   | 10/617,708  | BEERWERTH ET AL.            |  |  |  |  |  |
| Office Action Summary  | Examiner  | Art Unit                    |  |  |  |  |  |
|  | Gail Verbitsky  | 2859                        |  |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply   |   |                             |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |                             |  |  |  |  |  |
| Status   |   |                             |  |  |  |  |  |
| 1) Responsive to communication(s) filed on 08 Ju   | 1)⊠ Responsive to communication(s) filed on <u>08 June 2004</u> . |                             |  |  |  |  |  |
| 2a) This action is <b>FINAL</b> . 2b) ⊠ This   | · · · · · · · · · · · · · · · · · ·                               |                             |  |  |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.   |   |                             |  |  |  |  |  |
| Disposition of Claims  |   |                             |  |  |  |  |  |
| 4) ☐ Claim(s) 1-10 and 12-19 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration.  5) ☐ Claim(s) is/are allowed.  6) ☐ Claim(s) 1-6,9,10 and 12-19 is/are rejected.  7) ☐ Claim(s) 7 and 8 is/are objected to.  8) ☐ Claim(s) are subject to restriction and/or election requirement.   |   |                             |  |  |  |  |  |
| Application Papers   |   |                             |  |  |  |  |  |
| 9)☐ The specification is objected to by the Examine  | r.  |                             |  |  |  |  |  |
| 10) The drawing(s) filed on is/are: a) acce  | epted or b) $\square$ objected to by the E                        | Examiner.                   |  |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |   |                             |  |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |                             |  |  |  |  |  |
| Priority under 35 U.S.C. § 119   |   |                             |  |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.  |   |                             |  |  |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 4)  Interview Summary<br>Paper No(s)/Mail Da                      | nte                         |  |  |  |  |  |
| 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date   |   | atent Application (PTO-152) |  |  |  |  |  |

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### **DETAILED ACTION**

## Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claims 1, 14, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seacord et al. (U.S. 5167235) [hereinafter Seacord].

Seacord discloses in Figs. 1c and 2 a device/ protective cap for a temperature-measuring probe introducible in an ear cavity. The cap comprises a sheath 16 comprising an IR transparent window 42 and a base body 50 provided with additional structures: insulation 34 and the sheath 16. The cap shaped to be inserted in an ear canal (body cavity). The window is thin (reduced thickness) to be transparent to the IR (col. 5, line 47)

With respect to the preamble of claims 1 and 17: the preamble of the claims does not provide enough patentable weight because it has been held that a preamble is denied the effect of a limitation where the claim is drawn to a structure and a portion of the claim following the preamble is a self-contained description of the structure not depending for completeness upon the introductory clause. Kropa v. Robie, 88 USPQ 478 (CCPA 1951).

With respect to claim 14, using the particular material, i.e., plastic, to make the base, absent any criticality, is only considered to be the "optimum" material

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that a person having ordinary skill in the art at the time the invention was made using routine experimentation would have found obvious to provide for the base disclosed by Seacord since it has been held to be a matter of obvious design choice and within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use of the invention. In re Leshin, 125 USPQ 416.

- Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the base in the device disclosed by Seacord of a plastic because this particular material is commonly used to make housings/ caps for tympanic thermometers.
- 3. Claims 1 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suszynski et al. (U.S. 5018872) [hereinafter Suszynski].

Suszynski discloses in Figs. 2, 6-7 a device/ protective cap for a temperature-measuring probe; the probe has a base body 13 that is fit to be introduced in an ear cavity. The cap comprises a base body 13 which is provided with additional structures: a stretchable, resilient polyethylene IR transparent plastic film 43 of a cover/ cap 41 and a plastic tube 17, wherein the film 43 is placed over the plastic tube 17. The plastic tube 17 of the cap has a roughened texture to minimize a heat transfer (col. 5, lines 3-16) and thus, serving as an insulation. There are air pockets (chambers) 51, as shown in Fig. 7, formed by the film 43 and the plastic tube/ insulation 17. The air chambers 51 have their outsides close to the body cavity. Suszynski also teaches a holding device/ carrier 45 to hold the plastic tube 17 and the film 43, as shown in Fig. 2

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and in col. 4, lines 53-57, so as the film is stretched over a window (open end) 19 (col. 4, lines 63-65).

With respect to the preamble of claims 1 and 17: the preamble of the claims does not provide enough patentable weight because it has been held that a preamble is denied the effect of a limitation where the claim is drawn to a structure and a portion of the claim following the preamble is a self-contained description of the structure not depending for completeness upon the introductory clause. Kropa v. Robie, 88 USPQ 478 (CCPA 1951).

4. Claims 2, 9, 15-16, 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seacord in view of Wortz (U.S. 3581570).

Seacord discloses a device as stated above.

Seacord does not explicitly teach that the insulation is a foam, as stated in claim 2, in combination with the remaining limitations of claims 2, 9, 15-16, 19.

Wortz discloses a device in the field of applicant's endeavor wherein the insulation made a closed cell (closed pores) soft and inherently porous foam (foamed rubber or polyurethane) 94 so as to better conform the ear canal.

For claim 16: it is inherent that being a foam, the cap is not shaped prior to insertion to the ear canal, but only after. Therefore, the cap can expand/ stretch to obtain the necessary shape only when it is inserted into the body cavity, and thus, not prior to being positioned onto the probe.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to replace the insulation material, disclosed

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by Seacord, with a foam insulation, as taught by Wortz, so as to make the device soft and more comfortable for patient, especially for the patients with severe inflammatory process.

5. Claim 2-6, 9-10, 15-16, 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suszunski in view of Wortz (U.S. 3581570).

Suszynski discloses a device as stated above.

Suszynski does not explicitly teach that the insulation is a foam, as stated in claim 2, in combination with the remaining limitations of claims 2-6, 9-10, 15-16 and 19.

Wortz discloses a device in the field of applicant's endeavor wherein the insulation made a closed cell (closed pores) soft and, inherently, at least at some degree porous, foam (foamed rubber or polyurethane) 94 so as to better conform the ear canal.

For claim 16: it is inherent that being a foam, the cap is not shaped prior to insertion to the ear canal, but only after. Therefore, the cap can expand/ stretch to obtain the necessary shape only when it is inserted into the body cavity, and thus, not prior to being positioned onto the probe.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to replace the insulation material, disclosed by Suszynski, with a foam insulation, as taught by Wortz, so as to make the device soft and more comfortable for patient, especially for the patients in pain and with severe inflammatory process.

7. Claim 12 rejected under 35 U.S.C. 103(a) as being unpatentable over Suszunski and Wortz as applied to claims 2-6, 9-10, 15-16 above, and further in view of Lin.

Suszunski and Wortz disclose the device as stated above in paragraph 6.

They do not teach the limitations of claim 12. They do not explicitly teach that the window film is stretched by means of a holding device by clamping.

Lin discloses in Figs. 5, 8 a device wherein a window film 83 is held by means of an annular holding device A which is clamped to a tubular body B (the numerals A-B have been added by the Examiner, see attachment to the previous Office action, 03/11/2004).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the holding device, disclosed by Suszynski and Wortz, so as to have clamps to clamp the film to the tubular body (plastic tube), as taught by Lin, so as to provide a better stretch of the film over the window, in order to eliminate wrinkles, and thus, to provide more accuracy in measurements.

8. Claim 13, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suszynski in view of Bohrn et al. (U.S. 4775586) [hereinafter Bohrn].

Suszynski discloses the device as stated above.

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Suszynski does not teach a hot pressing or hot stamping operation to make the cap, as stated in claims 13, 18.

Bohrn teaches that using a method of hot pressing for a film, a desired transparency to an electromagnetic radiation (including IR) can be obtained.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a method of hot pressing, to provide a transparent window of the device disclosed by Suszynski, with a desired transparency, i.e., to IR, as taught by Bohrn, because this method is commonly used to obtain a desired transparency in plastic films.

9. Claim 13, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seacord in view of Bohrn et al. (U.S. 4775586) [hereinafter Bohrn].

Seacord discloses the device as stated above.

Seacord does not teach a hot pressing or hot stamping operation to make the cap, as stated in claims 13, 18.

Bohrn teaches that using a method of hot pressing for a film, a desired transparency to an electromagnetic radiation (including IR) can be obtained.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a method of hot pressing, to provide a transparent window of the device disclosed by Seacord, with a desired transparency, i.e., to IR, as taught by Bohrn, because this method is commonly used to obtain a desired transparency in plastic films.

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# Allowable Subject Matter

10. Claims 7-8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

## Response to Arguments

11. Applicant's arguments with respect to claims 1-10, 12-19 have been considered but are moot in view of the new ground(s) of rejection.

#### Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The prior art cited in the PTO-892 and not mentioned above disclose related devices and methods.

Any inquiry concerning this communication should be directed to the Examiner Verbitsky who can be reached at (571) 272-2253 Monday through Friday 8:00 to 4:00 ET.

**GKV** 

Gail Verbitsky

Primary Patent Examiner, TC 2800

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August 10, 2004